

REMARKS

In the Office Action dated May 18, 2004, the Examiner noted a typographical error in claim 18, which has been corrected.

Claims 2-8 and 10-18 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 7, 17 and 18 were rejected under 35 U.S.C. §112, first paragraph because the Examiner stated the description of the biochips being sensitive for multiple biomolecular markers, and the phrase "follow-up diagnostic data as a training dataset" is considered new matter. Claims 2-8 and 9-18 also were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement.

No rejection based on prior art was made.

All of the above rejections are respectfully traversed for the following reasons.

Addressing first the use of the term "sensitivity" in the claims, this term is being used in accordance with its normal dictionary definition and the definition which scientists understand with respect to any type of detector device. For reasons unknown to the present Applicants, the Examiner appears to have an grafted a need for some type of level or criteria to be associated with the term "sensitive." The term is being used to mean no more then the fact that the biochip is able to detect, or react to, certain types of biomarkers. It is not being used any differently than the way one would refer to a thermometer as being sensitive to temperature or a photocell as being sensitive to light. The relationship to the biomarkers is described in the paragraph bridging pages 2 and 3 of the present application wherein the biochip is stated to contain a marker array that can include a "hidden" markers in addition to approved markers. The "hidden" markers are not being used for making a current

diagnostic decision, but nevertheless information therefrom can be measured and recorded for possible future use.

It is only the Examiner, and not the Applicants, who has (for unknown reasons) apparently determined that some type of selection criteria/threshold value must be described in order to make the term "sensitive" meaningful. No such selection criteria or threshold value are necessary in order to allow the term "sensitive" to have a common and well-understood meaning in everyday conversation, and therefore no further explanation in the present application is necessary in order for the term "sensitive" to be easily understood by those of ordinary skill in the art.

The issues relating to new matter, lack of enablement, and failure to satisfy the written description requirement are all based on common factors, and therefore will be addressed together in the following discussion. First, as repeatedly argued in Applicants' previous responses, it cannot be stressed heavily enough that the details of the expert rules that are set forth in the claims of the present application have never been regarded by the Applicants as a part of their invention. The Applicants consider the distinguishing features of their invention with respect to the prior art to be in the data gathering and compilation and the ability to perform networked transmission of data to an expert system. What happens within the expert system after the data are supplied to it is of consequence to the present invention only because (naturally) it is hoped that the inventive data compilation will result in an improvement in the output of the expert system (neural network). The only reason why the original claims of the present application referred to a "new" expert rule (now changed to a "modified expert rule") is because this is necessary to describe an

operative, and therefore complete, method or system in the claims. How the modified rule is created is of no consequence to the present invention, and therefore the details of the actual rules employed in the expert system also are in consequential to the present invention. It is only necessary to be able to ascertain whether the inventive data gathering has resulted in an improvement in the output of the expert system, and therefore this is the only reason why reference to a "modified rule" has been made in the claims.

As the Examiner has noted, the ability to determine when the output of the expert system is improved must be ascertainable, however there are hundreds if not thousands of ways that this can be undertaken. An example is given in the present specification in the paragraph bridging pages 7 and 8, wherein a false negative or a false positive result is known to have occurred, in which case the patient is referred to a clinic for further evaluation, such as for conducting a biopsy. The biopsy analysis will determine the actual result, and therefore this actual result can therefore be entered into the expert system so that the expert system can "learn" what the correct outcome should have been. This also addresses the Examiner's questions regarding the lack of enablement of follow-up information, which is explicitly described in this same paragraph in the present specification.

The Examiner requested a specific example be given with regard to the Mendoza et al reference, however, Applicants have never contended that the Mendoza et al reference describes, or is intended to describe, an expert system or a neural network. The Anderson et al reference, however, not only describes such a system, but also claims such a system, and does so at no higher level of detail than is found in the present specification. Like the present application, the Anderson et al

patent is directed to improving the output of a neural network by improving the quality of the data that are entered into the neural network. In terms of the actual operation of the neural network itself, however, the Anderson et al reference relies on the knowledge of those of ordinary skill in the art, just as do the present Applicants. The only description in the entirety of the Anderson et al reference that generally refers to the internal operation of the neural network is found at column 27, line 63 through column 28, line 4, wherein it is stated that the neural network can be trained using any standard neural network training rule. The Anderson et al reference is concerned with using such a neural network for classifying images, and therefore this passage in Anderson et al also describes a simple criteria for determining whether improvement exists, namely by simply noting whether an error between the outputs of the neural network and the desired outputs of the network has decreased. In the specific context of image evaluation, Anderson et al provide many different statistical evaluations that can be undertaken, in column 30, lines 23-54. Since many of these are general statistical parameters, they have wide applicability even outside of the area of image classification. Many of these criteria, if desired, could be used to determine whether the output of the expert system in the present application has improved. The voluminous list of prior art in the Anderson et al patent includes many articles that also describe such criteria.

In the context of the present application, determining whether an improvement occurred need be no more complicated than noting that a known and used expert rule has a 90% probability of being a correct diagnosis, in which case an improved diagnostic value will mean a probability of correct diagnosis higher than 90%, using a modified expert rule. As noted above, the number of false positives or false

negatives that occur, that are judged against follow-up information, such as from a biopsy, can be used to "count" the percentage of occurrences of correct and incorrect findings.

In summary, Applicants respectfully submit the Examiner is hugely over-complicating Applicants' claimed subject matter, by looking for factors that Applicants never intended to include as part of their invention, as well as by underestimating the level of knowledge possessed by those of ordinary skill in this field regarding the use of expert systems/neural networks.

The details of the data gathering that Applicants regard as their invention are set forth in the figures, specifically in the flow chart shown in Figure 2. It is noted that even in the Anderson et al reference, nothing resembling a flow chart is even shown, thereby providing further evidence that in order to claim subject matter in this field, Applicants have exceeded the level of disclosure that is present in many issued patents.

All claims of the application are therefore submitted to in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,



(Reg. 28,982)

SCHIFF, HARDIN LLP
CUSTOMER NO. 26574
Patent Department
6600 Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606
Telephone: 312/258-5790
Attorneys for Applicants.